

AD _____

Award Number: W81XWH-08-2-0045

TITLE: Military to Civilian RCT of an Intervention to Promote Post-Deployment Reintegration

PRINCIPAL INVESTIGATOR: Dr. Nina Sayer

CONTRACTING ORGANIZATION: Minnesota Veterans Research Institute
Minneapolis, MN 55417

REPORT DATE: October 2011

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

*Form Approved
OMB No. 0704-0188*

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE (DD-MM-YYYY) 01-10-2011	2. REPORT TYPE Annual	3. DATES COVERED (From - To) 2 SEP 2010-1 SEP 2011 4. TITLE AND SUBTITLE Military to Civilian RCT of an Intervention to Promote Post-Deployment Reintegration 6. AUTHOR(S) Dr. Nina Sayer E-Mail: nina.sayer@va.gov		
			5a. CONTRACT NUMBER	
			5b. GRANT NUMBER W81XWH-08-2-0045	
			5c. PROGRAM ELEMENT NUMBER	
			5d. PROJECT NUMBER	
			5e. TASK NUMBER	
			5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Minnesota Veterans Research Institute Minneapolis, MN 55417			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSOR/MONITOR'S ACRONYM(S)	
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited				
13. SUPPLEMENTARY NOTES				
14. ABSTRACT This study seeks to determine whether Internet-Based Expressive Writing (IB-EW), a brief, low-cost, easily disseminated, and resource-efficient intervention, can reduce psychological symptoms and improve functioning among veterans returning from hazardous deployments. Although Expressive Writing's evidence-base is strong in civilian populations, its efficacy in combat veterans has not been tested. Nevertheless, Expressive Writing, as a highly private, readily accessible, and non-stigmatizing intervention, holds exceptional promise in overcoming barriers to mentally distressed veterans' help-seeking. We expect to further increase the accessibility of the intervention by delivering it over the internet (Internet-Based Expressive Writing). Long term objectives of this line of research are to develop and implement efficient, accessible, and effective interventions that facilitate combat deployment-to-civilian life transitions, thereby reducing risk of long-term, military-related psychopathology and disability. Toward that end, the study will also attempt to identify individual difference characteristics related to the efficacy of the treatment, to indicate who is most likely to benefit from the treatment in order to inform treatment implementation strategies.				
15. SUBJECT TERMS Research Study, Randomized Controlled Trial, Expressive Writing, Internet-based Intervention, OEF/OIF Veterans, Post-deployment Reintegration				
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 17
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	19a. NAME OF RESPONSIBLE PERSON USAMRMC 19b. TELEPHONE NUMBER (include area code)	

Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	7
Reportable Outcomes.....	14
Conclusion.....	14
References.....	15
Appendix A.....	16

INTRODUCTION:

This study seeks to determine whether Internet-Based Expressive Writing (IB-EW)¹, a brief, low-cost, easily disseminated, and resource-efficient intervention, can reduce psychological symptoms² and improve functioning³⁻⁵ among Veterans returning from hazardous deployments. Although Expressive Writing's evidence-base is strong in civilian populations⁶, its efficacy in combat Veterans has not been tested. Nevertheless, Expressive Writing, as a highly private, readily accessible, and non-stigmatizing intervention, holds exceptional promise in overcoming barriers to mentally distressed Veterans' help-seeking. We expect to further increase the accessibility of the intervention by delivering it over the internet (Internet-Based Expressive Writing). Long term objectives of this line of research are to develop and implement efficient, accessible, and effective interventions that facilitate combat deployment-to-civilian life transitions, thereby reducing risk of long-term, military-related psychopathology and disability. Toward that end, the study will also determine who is most likely to benefit from Internet-Based Expressive Writing in order to inform treatment implementation strategies.

BODY:

This section of the Annual Report is organized according to the study's Statement of Work (SOW) for Years 1, 2, and 3 (months 1-36), which appear throughout this section in underlined font.

Milestone 1: Preparing for Implementation (Month 1-12)

We continued to address remaining tasks for Milestone 1 during Year 3. With the exception of certain ongoing tasks (e.g., quarterly roster pulls), all Milestone 1 tasks are now completed; Main Study implementation began in June 2011.

Task 1: Obtain required approvals (Months 1-9)

- VA and DoD IRB & R&D approvals (Month 1-6)

Initial human subjects protection approvals and annual continuing review approvals were obtained in past reporting periods.

During the current reporting period, we obtained VA IRB continuing review approval in April 2011. We submitted DoD HRPO continuing review materials in May 2011; as of the end of the current reporting period, these materials remained under review.

• VA Central Office approval to obtain real SSNs and address information (Month 6-9)
Completed in Year 1.

• VA Central Office approval to access OIF/OEF Roster (Month 6-9)
Completed in Years 1 and 2.

• OMB Exemption for Research (Month 6)
Completed in Year 1.

- Web Ops review of project web application and posting of application on the VA Web Ops server (Month 6-9).

Completed in Years 1 and 2.

Task 2: Obtain address information for VA and nonVA users (Month 10-12)

After obtaining a sample of pilot participants (“Pilot 1”, n=785) and their address information in Year 2, we obtained a second pilot roster (“Pilot 2”, n=800) with address information during the current reporting period. We sent pilot recruitment materials to half (n=400) of these cases, and determined that further piloting was unnecessary. The other half (n=400) were then re-assigned to the Main Study cohort.

Through our pilot work, we learned that a much lower proportion of OEF-OIF Veterans responded to recruitment mailings, met study eligibility criteria, and agreed to participate than expected. We therefore obtained IRB approval to increase the size of our recruitment sample for the Main Study from 6,000 to 20,000, and revised study procedures to complete the Main Study recruitment in 12 months rather than the 15 months originally proposed. As such, we made arrangements to obtain four quarterly roster pulls (each n=5,000) for recruitment. **During the current reporting period, we obtained the first two of four roster pulls (total n=10,000), including address information.**

Task 3: Investigator kick-off meeting at Minneapolis VAMC (Month 11)

Completed in Year 1.

Task 4: Pilot procedures for recruitment and participant tracking (Months 10-12)**Product: Web-based application and study procedures ready for roll-out**

Pilot recruitment began at the end of the previous reporting period, in August 2010, and continued into the current reporting period. We sent recruitment materials to n=785 Pilot 1 participants between August 2010 and November 2010. After revising study methods, materials, and procedures based on these data, we implemented a second round of piloting (Pilot 2, n=400), recruiting this cohort between February 2011 and April 2011.

Following a final round of revisions based on Pilot 2 data, **the study's methods, materials, and procedures – including the study website and our internally-developed participant tracking application – were finalized for Main Study implementation in June 2011**. Main Study recruitment and enrollment began that same month.

Milestone 2: Data Collection (Month 13-36)

Pilot and Main Study data collection began during the current reporting period. Enrollment in the two pilot cohorts began in September 2010 and March 2011, respectively. **Main Study participants began enrolling in June 2011.**

Task 5: Contact 384 OIF/OEF veterans per month using mail recruitment strategy (Month 13-27)

During Pilot 1 recruitment, we contacted approximately n=100 Veterans per week, to approximate the intended n=384 Veterans per month proposed for Main Study recruitment. Due to the unexpectedly low recruitment response, eligibility, and participant enrollment rates observed in Pilot 1, we increased our recruitment rate in Pilot 2, contacting approximately n=200 Veterans per week. We also obtained IRB approval to increase the overall number of Main Study recruitments from n=6,000 to n=20,000 and adopted procedures to complete Main Study recruitment in 12 months rather than the proposed 15 months. After two initial Main Study recruitment mailings of n=200 each, we ramped up to our revised recruitment rate, thereafter **contacting approximately n=384 new Veterans per week (n=1,667 per month) for recruitment**. Through the end of the current reporting period, Main Study recruitment mailings were sent to a total of n=4,082 Veterans.

Task 6: Randomize 78 OIF/OEF per month to three study arms (26 per study arm per month) (Month 13-27)

During the current reporting period, we enrolled n=149 Main Study participants between 6/30/11 and 8/31/11, which translates into a **randomization rate of approximately 74 per month**. We also randomized n=22 Pilot 1 participants and n=18 Pilot 2 participants during the current reporting period.

For the Main Study cohort, we implemented an imbalanced randomization allocation plan (2 Expressive Writing : 2 Control Writing : 1 No Writing) to maximize our ability to detect group differences between the two writing groups. From 6/30/11-8/31/11, we randomized 58 Expressive Writing participants (approx. 29/mo.), 60 Control Writing participants (approx. 30/mo.), and 31 No Writing participants (approx. 15/mo.) in the Main Study cohort (see table immediately below).

Main Study randomizations by cohort and study arm:

	Total	Expressive Writing	Control Writing	No Writing
Main Study	149	58	60	31
Pilot 2	18	6	5	7
Pilot 1	22	7	8	7

Task 7: Participants receive copy of study schedule through email (Months 13-27)

Participants set their own study schedule on the study website after being randomized into a study condition during the online consent process. Once a participant saves his/her session schedule on the study website, we automatically email a copy of the session schedule to him/her and mail him/her a packet of information about the study that includes his/her session schedule.

Task 8: Each month, 78 participants complete baseline assessments (Month 13-27)

Of the n=149 Main Study participants who enrolled between 6/30/11 and 8/31/11, n=134 completed the baseline session, which translates into a **rate of approximately 67 participants completing baseline assessments per month**. Of the n=22 Pilot 1 and n=18 Pilot 2 participants who were randomized, n=13 and n=18 completed baseline sessions, respectively.

Task 9: Each month, 78 participants in EW and 78 participants in CW conditions complete writing assignments (Month 13-27)

Of the n=58 Main Study participants who were randomized to the Expressive Writing condition, n=50 completed their baseline assessment and were eligible to proceed to their four sessions of writing. These individuals collectively completed 146 writing sessions between 6/30/11 and 8/31/11, a **rate of approximately 73 Expressive Writing sessions per month**.

Of the n=60 Main Study participants who were randomized to the Control Writing condition, the n=55 who completed their baseline assessment proceeded to submit a total of 138 writing sessions between 6/30/11 and 8/31/11, a **rate of approximately 69 Control Writing sessions per month**.

In the Pilot 1 cohort, the n=5 EW and n=4 CW participants who completed baseline sessions proceeded to complete 13 and 7 writing sessions, respectively. In Pilot 2, the

n=6 EW and n=5 CW participants who completed baseline sessions completed 16 and 12 writing sessions, respectively.

Task 10: Review essays to assess risk of harm to self or other (Month 13-27)

All writing samples submitted online were reviewed to assess for elevated risk of harm to self or others.

Of the 284 writing samples submitted by Main Study participants during the current reporting period and reviewed for possible risk elevation, three were deemed to possibly confer elevated safety risk and were referred to the study's independent Risk Assessor for further assessment. Two of these yielded non-emergency outreach and resource referrals; one was deemed not to require any further response.

None of the 20 Pilot 1 or 28 Pilot 2 writing samples contained indications of elevated safety risk.

Task 11: Participants receive emails and letters reminding them to complete 3-month follow up assessment. Participants complete 3-month follow up assessment online (Month 16-30).

Two reminder emails and two reminder mailings were sent to each Pilot 1 and Pilot 2 participant prior to their 3-month follow-up sessions. No Main Study participants have yet reached their 3-month follow-up reminder dates.

Task 12: Participants receive emails and letters reminding them to complete 9-month follow up assessment. Participants complete 9-month follow up assessment online (Month 22-36).

Two reminder emails and two reminder mailings were sent to each Pilot 1 participant prior to their 9-month follow-up sessions. For Pilot 2 and the Main Study cohorts, the final assessment occasion was changed to a 6-month rather than 9-month follow-up; this change was approved by IRB. Pilot 2 participants who reached their reminder dates each received two reminder emails and two reminder mailings prior to their scheduled 6-month follow-up sessions. No Main Study participants have yet reached their 6-month follow-up reminder dates.

Task 13: Contact of participants who fail to complete 3-month and/or 9-month follow up assessments as scheduled (Month 16-36).

No Main Study participants have yet reached their 3- or 6-month follow-up reminder dates, and therefore no missed follow-up session reminders have yet been implemented for the Main Study cohort. For the Pilot 1 and 2 cohorts, all participants who missed a follow-up assessment session received outreach according to the established procedures for their cohort, including email, postcard, and/or telephone reminders.

KEY RESEARCH ACCOMPLISHMENTS:

Recruitment and Enrollment

First Pilot Cohort ("Pilot 1")

1. We began recruiting for piloting at the end of the previous reporting period and continued into the current reporting period. We sent recruitment mailings to n=785 Veterans in the Pilot 1 cohort between August 2010 and November 2010. Of these, n=104 logged-in to the study website to complete eligibility questions, n=33 met eligibility criteria, and n=22 completed the online consent process and

- were randomized to a study arm during the current reporting period. The recruitment response, eligibility, and enrollment rates for Pilot 1 were lower than expected.
2. We obtained feedback about the study from a number of Pilot 1 participants who had enrolled in the study as well as some who were recruitment non-responders. In addition to general feedback about the study and its website, we specifically sought feedback related to recruitment and enrollment methods and materials in order to inform possible revisions to improve our response rate.
 3. Based on Pilot 1 implementation and feedback obtained from a subset of participants, we gained approval for a series of IRB amendments aimed at improving our recruitment methods, consent/enrollment process, and other study procedures. We also secured approval to contact up to n=800 additional pilot participants to test these revised procedures.

Second Pilot Cohort (“Pilot 2”)

4. We received approval to recruit up to n=800 additional pilot participants following Pilot 1. Of these, we ultimately contacted n=400 Pilot 2 Veterans for recruitment between February 2011 and April 2011.
5. In preparation for our Pilot 2 roster creation, we learned that we could obtain both VA users and non-users from VA’s Environmental Epidemiology Services (EES), whereas for Pilot 1 we had obtained roster data for VA users and non-users separately, from VA’s VHA Support Service Center (VSSC) and the DoD’s Defense Manpower database maintained by VA’s EES office, respectively. The Pilot 2 roster pull was implemented exclusively by EES, as were all future roster pulls (i.e., Main Study roster pulls).
6. During Pilot 2, we identified further revisions to study procedures that were submitted to IRB and approved, including the addition of further outreach methods during enrollment and study participation aimed at increasing recruitment, enrollment, and retention rates (e.g., notifying Veterans of their eligibility by phone call in addition to email).
7. After recruiting n=400 of the n=800 Veterans in the Pilot 2 roster, we determined that sufficient efforts had been devoted to piloting and that it would be preferable to focus on Main Study implementation rather than continuing to pilot. The remaining n=400 Veterans were instead reserved for the Main Study and later comprised the first two recruitment waves of that cohort.
8. Of the n=400 Veterans recruited for Pilot 2, n=182 returned a mailed eligibility survey, n=53 met eligibility criteria and were invited to participate, n=24 logged-in to the study website to complete the consent process, and n=18 consented to participate and were randomized to a study arm.

Main Study

9. Because our recruitment response, eligibility, and enrollment rates were lower than expected during piloting, we obtained IRB approval to increase the number of Veterans to contact for Main Study recruitment from n=6,000 to n=20,000. As well, because we were behind schedule vis-à-vis the study’s Statement of Work, we adjusted our recruitment schedule to be completed in 12 months rather than 15 months and shifted the final follow-up session from 9- to 6-months post-baseline to reduce potential attrition and further compress the total length of study implementation.
10. We initiated request procedures for Main Study roster pulls to meet these revised recruitment plans; specifically, we requested four quarterly pulls of

- n=5,000 from VHA's EES. We obtained our first Main Study roster pull in June 2011 and initiated Main Study recruitment that same month, using the remaining n=400 Veterans from our previous Pilot 2 roster pull for our first two recruitment waves and implementing our standard Main Study recruitment weekly waves of approximately n=384 thereafter. We obtained our second quarterly Main Study roster pull during the current reporting period as well.
11. After reviewing the study's stratification plan and within-strata participation rates from piloting, we identified a new stratification plan for the Main Study for the random selection of OEF/OIF Veterans. Beginning with the Main Study, we no longer stratified by VA user status or race, but by gender only. We proportioned gender 70:30 male:female rather than 50:50 as during piloting. This was to more closely match our sample to the population while still oversampling female Veterans to allow sufficient statistical power to detect gender effects.
 12. We revised our procedures for randomizing consented participants to study arms for the Main Study based on a review of our participation rates during piloting. Our randomization procedures now allocate participants at a rate of 2:2:1 EW:CW:NoW rather than the rate of 1:1:1 used during piloting. This is to ensure that a sufficient number of participants are randomized to the two writing conditions to maximize our ability to detect differences between these two groups, the comparison that is of primary interest.
 13. Of the n=4,082 Veterans recruited for the Main Study through the end of the reporting period, n=1,007 returned a mailed eligibility survey, n=340 met eligibility criteria and were invited to participate, n=169 logged-in to the study website to complete the consent process, and n=149 consented to participate and were randomized to a study arm (n=58 Expressive Writing, n=60 Control Writing, and n=31 No Writing).
 14. It is worth noting that because Main Study enrollment is ongoing, the figures in the preceding point are underestimates of the actual recruitment response, eligibility, and enrollment rates we are obtaining in the Main Study. It takes time for recruitment mailings to be received by the Veterans and for their eligibility forms to be return-mailed to us, and Veterans do not always log-in to the study website to enroll immediately upon being informed that they are eligible for the study. For example, we have observed that significant numbers of eligibility surveys continue to be returned by participants in a given mailing cohort for at least six weeks after their first recruitment mailing. As such, although the overall rate of eligibility survey return through the end of the reporting period was 25% (1007/4082), when considering just Veterans whose initial mailing was sent at least six weeks before the end of the reporting period, the rate was 46% (623/1344).

Study Implementation

15. Throughout Pilot 1, Pilot 2, and the Main Study to date, we implemented study procedures, including:
 - monitoring our study's toll-free phone number and US mail communications and responding to participant/respondent inquiries as appropriate.
 - obtaining and compiling sufficient materials and resources to implement study recruitment, enrollment, and other outreach procedures.
 - sending initial recruitment mailings to approximately n=384 new Veterans per week, plus additional recruitment mailings to Veterans whose previous mailings had been returned undeliverable and for whom

- we had obtained new contact information; we therefore sent approximately n=500 total initial recruitment mailings per week.
- sending weekly 2- and 4-week follow-up recruitment mailings to Veterans who did not respond to the first mailing.
 - monitoring participants' session adherence and implementing planned outreach procedures for missed sessions as needed.
 - conducting additional outreach with Veterans per the study protocol, including mailings (e.g., post-scheduling mailings), emails (e.g., upcoming and missed session reminders), and phone calls (e.g., post-eligibility phone calls).
 - developing a set of scannable paper-and-pencil versions of follow-up survey materials to mail to participants who are unable to complete follow up sessions online, having these "Teleform" versions printed, and mailing them to participants as needed.
 - periodically retrieving study data submitted on the website from VA Web Ops and reviewing for quality assurance.
 - collecting process and resource investment data to inform cost analysis and process evaluation procedures in the future.
16. Per the study's IRB-approved Safety Manual, the study coordinator read all pilot participants' writing samples that were submitted online to assess for indications of elevated safety risk throughout Pilot 1, Pilot 2, and Main Study to date. There have been no difficulties retrieving these data from VA Web Ops servers, transferring to secure local servers, and accessing them locally to review. Of the 332 writing samples submitted by participants in the three study cohorts, three were identified as possibly conferring elevated risk and were referred to the study's outside Risk Assessor; none were deemed indicative of imminent risk requiring emergency intervention.
17. Although we initially proposed to use keyword scanning software to identify indicators of risk in participant writing samples, it became clear during piloting that this procedure would yield a high rate of false positives and could miss cases with elevated safety risk. As such, all participant writing samples in all three study cohorts were read by the study coordinator for risk.

Pilot 1

18. In Pilot 1, n=22 participants were randomized, including n=7 to the Expressive Writing, n=8 to the Control Writing, and n=7 to the No Writing conditions. Of these, n=13 completed the baseline assessment session and were eligible to continue with the study.
- Of the n=5 in the Expressive Writing condition who completed baseline, n=5 completed at least one writing session and n=2 completed all four writing sessions. A total of 13 Expressive Writing sessions were completed by Pilot 1 participants.
 - In the Control Writing condition, n=4 completed baseline and were eligible to continue with the study. Of these, n=3 completed at least one Control Writing session and n=1 completed all four. These individuals completed a total of 7 writing sessions.
19. In Pilot 1, out of the n=13 participants who completed the baseline assessment session and were eligible to continue with the study, n=9 completed the 3-month follow-up session and n=4 completed the 9-month follow-up session.
20. Following Pilot 1, we gained IRB approval of several protocol amendments, including an amendment revising the study's writing instructions to improve

their user-friendliness and improve the relevance of the Control Writing instructions to the population, an amendment revising aspects of the online consent process, and an amendment updating aspects of the consent process.

Pilot 2

21. For Pilot 2, n=18 participants were randomized, including n=6 to the Expressive Writing, n=5 to the Control Writing, and n=7 to the No Writing conditions. All of them completed the baseline assessment session and were eligible to continue with the study.
 - Of the n=6 in the Expressive Writing condition, n=5 completed at least one writing session and n=3 completed all four writing sessions. A total of 16 Expressive Writing sessions were completed by the Pilot 2 EW participants.
 - In the Control Writing condition, n=5 completed baseline and were eligible to continue with the study. Of these, n=3 completed at least one Control Writing session, all of whom completed all four writing sessions.
22. In Pilot 2, out of the n=18 participants who completed the baseline assessment session and were eligible to continue with the study, n=8 completed their 3-month follow-up session and n=2 completed their 6-month follow-up session as of the end of the reporting period.
23. Following Pilot 2, we submitted a number of protocol amendments to IRB that were approved, including minor revisions to study measures and alterations to study outreach procedures aimed at improving our participation rates.

Main Study

24. As of the end of the reporting period, n=149 Main Study participants had been randomized, including n=58 to Expressive Writing, n=60 to Control Writing, and n=31 to No Writing. Of these, n=50, n=55, and n=29 (total n=134) completed their baseline assessment session, respectively, and were eligible to continue with the study.
 - Of the n=50 Expressive Writing participants who completed baseline, n=43 have completed at least one writing session and n=31 have completed all four. A total of 146 EW sessions were completed by Main Study participants during the current reporting period.
 - Of the n=55 Control Writing participants who completed baseline, n=45 have completed at least one writing session and n=29 have completed all four. A total of 138 CW sessions were completed by Main Study participants.
 - It is notable that, unlike the Pilot 1 and Pilot 2 cohorts which no longer have any participants in the writing phase of the study, Main Study participants continue to complete writing sessions. Of the Main Study participants who finished the writing phase of the study prior to the end of the reporting period, more than 80% completed all four sessions.
25. No Main Study participants had completed any 3- or 6-month follow-up sessions as of the end of the reporting period, as none had yet reached their scheduled follow-up dates.

Human Subjects Protection/IRB

26. We submitted VA IRB continue review materials in March 2011 and received continuing review approval in April 2011. We submitted DoD HRPO continuing

- review materials in May 2011; as of the end of the current reporting period, these materials remained under review.
27. During the current reporting period, we obtained IRB approvals for a number of protocol amendments, as described throughout the above sections.
 28. During the current reporting period, no serious adverse events (SAEs) occurred.

Internet Application

29. During the current reporting period, we periodically reprogrammed portions of the study website to reflect changes to study methods and materials:
 - Following Pilot 1, we reprogrammed the web application to reflect IRB-approved content and procedural changes, for example revising writing session programming to reflect changes to writing session instructions that were approved by IRB.
 - Similarly, the website was reprogrammed in response to revisions made following Pilot 2.
 - In all cases, such revisions were first developed on VA's web development servers (i.e., the intranet version of the website) while we continued to implement the extant version of the website on VA web production servers (i.e., the internet) uninterrupted for all study participants. Once changes were made on web development servers, the study team internally tested the performance of the revised web pages, identified any further revisions that were needed, and uploaded additional changes as necessary, until final versions were ready for implementation on the internet. Finalized versions were then uploaded onto VA internet servers for use by study participants.
30. For all study cohorts, we:
 - provided general information about the study on a publicly-accessible study home page, including a downloadable copy of the study brochure.
 - displayed an "I Need Help Right Away" link for distressed users on all study web pages, which navigates to a web page with contact information for the VA's Veterans Crisis Line and for the study team.
 - included a set of links to Veteran resources and other study-related information (e.g., the study website's privacy policy) on all study web pages.
 - maintained a secure web portal for participants to log-in to the study website using a unique username and password.
 - implemented an online consent process for Veterans who are eligible for the study to complete when logging-in to the study website for the first time.
 - automatically randomized participants to a study arm upon completing the online consent process.
 - provided a session scheduling page on the website for participants to set their study session schedule following randomization and to revise their session schedule as needed thereafter.
 - administered study measures to enrolled participants, collecting data online for baseline and follow-up assessment sessions.
 - assigned and displayed an incentive electronic gift card code to each participant upon completion of each assessment session and embedded a header on every study web page linking participants to a secure list of all incentive gift card codes earned to date.

- implemented online Expressive and Control Writing sessions for participants randomized to those conditions.
- successfully retrieved study data entered by participants on our website from VA Web Ops servers and saved to secure local servers.
- monitored activity on the study's website to facilitate study implementation.
- identified minor technical problems that occurred periodically, made necessary modifications to the study website, and notified affected users.
- responded to a small number of users who self-reported having technical difficulties and made minor modifications to the study website in response to problems that were identified (e.g., difficulty with the website's study session scheduling page related to server-side and client-side time zone issues).
- monitored web analytics data obtained from VA Web Ops web portal to assist in evaluating response rate and other study implementation issues (e.g., comparing visits to our website's log-in page vis-à-vis actual log-ins recorded by the servers).

Participant Tracking

31. During the current reporting period, we also reprogrammed portions of our internally-developed participant tracking application periodically to reflect changes to study methods and materials. For example, prior to the start of recruitment for each new study cohort, we reprogrammed the tracking application to accommodate the new cohort's procedures and added the ability to output separate reports for the new and existing cohort(s). In its final format, the tracking application now accommodates all three recruitment cohorts and all their respective methods and materials.
32. For all study cohorts, we populated the participant tracking application with data from VA Web Ops servers on a daily basis for project management purposes, using the tracking application to:
 - track individual participants over the course of their involvement in the study to coordinate participation activities.
 - maintain a secure study crosswalk to link individual participants and their study IDs.
 - monitor key participation rates in real time, including overall rates of log-in, eligibility, consent, randomization, scheduling, and session completion, as well as additional specific information such as response rates for specific eligibility screening items.
 - document general study notes, technical difficulties that were identified, and other study-related information.
 - generate semi-automated email communications to enrolled participants.
 - generate mail merge documents for mailed participant communications, such as recruitment and session reminder mailings.
 - document all returned (undeliverable) mailings, including return codes for different types of returned mailings.
 - display call lists of individuals needing specific types of telephone outreach (e.g., eligibility phone calls).
 - document all communications with study participants in a communication log embedded in the study's tracking application.
 - collect process and resource investment data for later evaluation.

33. During piloting, response rates monitored with our tracking application were used to inform revisions to study methods and materials, as described in previous sections.
34. For all three study cohorts, participant mailings that were returned as undeliverable were referred to the University of Minnesota Health Survey Research Center (HSRC) for assistance with identifying updated address information; materials were re-sent accordingly.

Administrative

35. During the current reporting period, we continued to meet regularly as a project team to coordinate project activities.
36. Study personnel reviewed writing samples for qualitative analytic purposes, primarily focusing on the identification of preliminary themes since data collection is ongoing.
37. We conducted preliminary analyses of Pilot 1 baseline and follow-up data.
38. Study personnel attended professional development trainings and participated in online webinars on topics relevant to the study, for example the use of distance technologies in VA clinical care and OEF-OIF Veteran mental health outcomes.
39. Select study personnel were trained in the Atlas.ti qualitative analysis software program.
40. The study team completed a research compliance audit with our facility's research compliance officer in May 2011.
41. We updated the study's entry in the U.S. National Institutes of Health's clinicaltrials.gov website as needed.
42. We submitted quarterly technical progress reports to DoD's U.S. Army Medical Research and Materiel Command.
43. We maintained a critical documents binder for the study, including both a paper version and an electronic backup copy of each document.
44. When Main Study recruitment was initiated, the study team met with key stakeholders, including our facility's OEF/OIF program team and clinical provider groups (e.g., the posttraumatic stress treatment program, mental health intake team, after hours psychiatric emergency personnel), to establish working relationships, gain expert feedback about OEF/OIF programming, and educate them about the project.
45. We are aware that the study is behind schedule and are planning to request a no-cost extension, as discussed with our previous Grant Officer's Representative Dr. Kimberly del Carmen, in a conference call in August 2010.

REPORTABLE OUTCOMES: (None)

CONCLUSION:

The most significant accomplishments of Year 3 were completion of pilot work and initiation of Main Study implementation. We completed an initial round of piloting, in which we learned that our recruitment response, eligibility, and enrollment rates were lower than expected. We revised a number of study procedures and implemented a second round of piloting to test these new procedures. This second round of piloting yielded a number of further revisions to the study protocol. In June 2011, we began recruiting for the Main Study. Because piloting indicated that our anticipated recruitment response,

eligibility, and enrollment rates had been overestimated, we substantially increased the number of recruitment mailings for the Main Study. As well, because the study is behind schedule, we made arrangements to complete study recruitment in 12 months instead of 15 months and reduced the final follow-up from 9-months to 6-months post-baseline in order to further compress the total length of study implementation. In the Main Study to date, we appear to be approximating our intended monthly enrollment and session completion targets. Participants who enroll in the study in general adhere to their session schedule, with a large majority completing their baseline and writing sessions. In the next reporting period, we will continue to closely monitor recruitment response rates and session completion rates to ensure we obtain sufficient pre- and post-intervention data to implement planned outcome analyses.

REFERENCES:

1. Pennebaker JW, Chung CK. (2007). Expressive writing, emotional upheavals, and health. In: Friedman H, Silver R, editors. *Foundations of health psychology*. New York, Oxford University Press. 2007. 263-284.
2. Hoge CW, Castro CA, Messer SC, McGurk D, Cotting DI, Koffman RL. (2004). Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. *N Engl J Med*, 351: 13-22.
3. Armstrong K, Best S, Domenici P. (2006). *Courage after fire: Coping strategies for troops returning from Iraq and Afghanistan and their families*. Berkeley, CA, Ulysses Press.
4. Browne T, Hull L, Horn O et al. (2007). Explanations for the increase in mental health problems in UK reserve forces who have served in Iraq. *Br J Psychiatry*, 190: 484-489.
5. Hutchinson JH, Banks-Williams L. (2006). Clinical issues and treatment considerations for new veterans: Soldiers of the wars in Iraq and Afghanistan. *Primary Psychiatry*, 13: 66-71.
6. Frattaroli J. (2006). Experimental disclosure and its moderators: A meta-analysis. *Psychological Bulletin*, 132: 823-865.

APPENDIX A: Statement of Work (SOW)

Milestone 1: Preparing for Implementation (Month 1-12)

Task 1: Obtain required approvals (Months 1-9)

- VA and DoD IRB & R&D approvals (Month 1-6)
- VA Central Office approval to obtain real SSNs and address information (Month 6-9)
- VA Central Office approval to access OIF/OEF Roster (Month 6-9)
- OMB Exemption for Research (Month 6)
- WebOps review of project web application and posting of application on the VA WebOps server (Month 6-9).

Task 2: Obtain address information for VA and nonVA users (Month 10-12)

Task 3: Investigator kick-off meeting at Minneapolis VAMC (Month 11)

Task 4: Pilot procedures for recruitment and participant tracking (Months 10-12)

Product: Web-based application and study procedures ready for roll-out

Milestone 2: Data Collection (Month 13-36)

Task 5: Contact 384 OIF/OEF veterans per month using mail recruitment strategy (Month 13-27)

Task 6: Randomize 78 OIF/OEF per month to three study arms (26 per study arm per month) (Month 13-27)

Task 7: Participants receive copy of study schedule through email (Months 13-27)

Task 8: Each month, 78 participants complete baseline assessments (Month 13-27)

Task 9: Each month, 78 participants in EW and 78 participants in CW conditions complete writing assignments (Month 13-27)

Task 10: Review essays to assess risk of harm to self or other (Month 13-27)

Task 11: Participants receive emails and letters reminding them to complete 3-month follow up assessment. Participants complete 3-month follow up assessment online (Month 16-30).

Task 12: Participants receive emails and letters reminding them to complete 9-month follow up assessment. Participants complete 9-month follow up assessment online (Month 22-36).

Task 13: Contact of participants who fail to complete 3-month and/or 9-month follow up assessments as scheduled (Month 16-36).

Milestone 3: Data Preparation (Month 37-39)

Task 14: Clean and merge assessments for data analysis (Month 37-38).

Task 15: Upload participant's essays into ATLAS.ti for coding (Month 37-40)

Task 16: Extract VA service use data for all participants from VA administrative databases; clean and merge data (Month 39)

Product: Data sets ready for analysis

Milestone 4: Data Analysis, Dissemination and Products (Month 40-48)

Task 17: Conduct statistical analyses to address primary hypotheses (Month 40-42)

Product: Tested web-based intervention for improving outcomes among OIF/OEF veterans with post-deployment reintegration problems that can be used throughout VA for very little expense.

Task 18: Code participant essays (Month 40-43)

Task 19: Analyze coded essays (Month 43-45)

Product: Catalogue of post-deployment reintegration challenges and needs from the perspective of OIF/OEF veterans that can be used to inform other interventions

Task 20: Dissemination and implementation plan meeting in Minneapolis (Month 43)

Task 21: Conduct statistical analyses to address secondary and exploratory hypotheses

(Month 43-45)

Task 22: Dissemination Activities/Products and Deliverables (Month 46-48)

- Manuscript preparation (Product)
- Report writing (Product)
- Executive summary preparation and distribution to DoD and VA stakeholders (Product)
- Presentations to DoD and VA stakeholders (Product)
- Presentations at scientific meetings (Product)